BAA-NIH-NIAID-NCRR-DMID-03-36
Amendment #1 (Questions & Answers)

This Amendment provides questions submitted by potential applicants/offerors and the responses provided by the NIAID. The responses are offered for information only and do not modify or become part of this solicitation. This Amendment will be updated at least weekly to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment #1 for additional Q&A.

All offerors are advised to revisit the original solicitation package as it incorporates some minor edits effective November 5, 2002. http://www.niaid.nih.gov/contract/archive/RFP0336-0.pdf

"Regional Biocontainment Laboratories (RBL) and National Biocontainment Laboratories (NBL)"

Amendment to Solicitation No.:	BAA-NIH-NIAID-NCRR-DMID-03-36
Amendment No.:	1 (3rd posting)
Issue Date:	November 5, 2002 (Questions 1 – 21) November 7, 2002 (Questions 22 – 27) November 25, 2002 (Revised Response to Question 27, and Questions 28 – 42)
Proposal Due Date/Time:	February 10, 2003, at 4:00 P.M., EST
Issued By:	Kristen Mistichelli Contracting Officer CMB/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 2230, Bethesda, Maryland 20892-7612
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Applicants/Offerors must acknowledge receipt of this Amendment #1 on each copy of the application/proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your application/proposal.

The hour and date specified for receipt of applications/proposals HAS NOT been extended.

The following answers are provided concerning a number of inquiries we have received for the above numbered acquisition:

Question 1 It is my understanding from reading the RFP that the parties that are awarded the contracts will own 100% of the building; however, NIH would control 100% of the activity in the building for 20 years. If a contractor contributes 25% of the cost of the building should the contractor be able to control 25% of the work done in that building?

No. See page 7, item 6 of the BAA. Additionally, the priorities for usage of the facilities are described on page 5, first paragraph of Parts A and B.

Question 2 Will the contractor be allowed to charge a profit on the construction of the building?

No. This solicitation has been issued to eligible non-profit organizations. Please note that any subcontract issued to for-profit construction companies can contain a reasonable fee/profit on the subcontract.

Question 3 Can the contractor stipulate in the proposal that it is contingent upon being awarded the operating contract?

We have significant concerns about building a facility and then having another contractor be awarded the contract to operate a facility on our campus. If we are responsible for security, safety and the overall operations then another company operating a facility we own is an issue.

The BAA is silent regarding an operations contract for the NBL except for pg 6 where it states that the awardee may "compete" for an operations contract. Previous information from NIAID had indicated the intent to award an operations contract simultaneously with the construction contract. Is this still the intent? If not, is it contemplated that the operations contract might be awarded to an institution that did not build the facility? When will the solicitation be released?

NBL awardees will be eligible to submit a separate proposal for support activities related to the operation and maintenance of the NBL.

Question 4 Can the government provide any assurance as to the level of contracts/grants placed in the RBL/NBL over the next 20 years?

No.

Question 5 If the contractor elects to propose on a RBL (grant based) instead of the NBL (contract based) how will it get a return on its investment through the grants?

See Question #2, above.

Question 6 Will the arrangement be that the contractor leases the building to NIH?

No.

Question 7 Will the contractor be able to depreciate the building and include that in their indirect rates?

The contractor should follow good accounting practices in accordance with that organization's approved accounting procedures and applicable laws and regulations.

Question 8 Will the contractor be able to charge per diems for animals in the facility?

Yes. See page 6, paragraph 1, of the BAA.

Question 9 We have significant concerns about the impact on insurance rates from the standpoint of increased risk related to doing BSL-4 work and also the possibility of conducting human clinical trials. If the contractor is unable to get reasonable insurance, is NIH willing to provide it? If the contractor is able to get insurance but at a much higher rate, can the premium associated to the new facility be charged to the projects conducted in that facility?

Insurance for the operation of the facility is outside of the scope of this announcement. The core costs of operating the facility will be included in a separate Operation and Maintenance contract. Insurance may be included as one of the core costs.

Question 10 How many principal investigators should such a facility support? I understood from the August briefing that I attended that up to 20 PIs could, in principal, utilize this facility at any one time. However, I understood that the construction grant does not allow for extensive contiguous conventional laboratory or office space. Is this true?

The Notice of Intent (NOT-AI-02-038) dated July 19, 200,2 and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. Personnel support for the operation of the facility is outside of the scope of this announcement. Minimum square footage for the NBLs is indicated on page 10 of the BAA. The size and capacity of the RBLs is not specified and is dependent upon the proposed usage. Contiguous conventional laboratory and office space are not excluded from the SOW, but should be kept to a minimum to support the BSL-3 and BSL-4 laboratories.

Question 11 What would be the anticipated scale of any clinical isolation capability? Again, from the briefing, I understood that this space should support 5 to 10 people, either for index case observation or in the event of accidental exposure within the rest of the RBL. Would one be able to justify considerably more clinical isolation space (10x)?

The Notice of Intent (NOT-AI-02-038) dated July 19, 2002, and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. Clinical facilities are not required for the RBLs. For the NBLs, clinical space is required that will support small-scale clinical trials, and a patient containment ward for accidentally exposed users. See page 10 of the BAA for square footage requirements. The NBLs should not include clinical space that would only be used in the event of a bioterrorism emergency.

Question 12 Can you comment on the current anticipated funding level for these projects and the timeline? Does this still reflect the thinking as presented in August? Is it still likely that NIH will sponsor the RBL contracts versus a Department of Homeland Security?

The August presentation was based on the information available at the time of the meeting. The requirements and timeline have evolved. The BAA should be consulted for current guidelines. The Legislation for the creation of the Department of Homeland Security has not been finalized.

Question 13 How does this solicitation change previously issued information in the Notice of Intent and at the August 8th meeting? I am specifically interested in the number of NBL awards (previously announced 5-7) and the budget (up to $100 million in construction). Is there any guidance regarding the number of RBLs vs NBLs?

The Notice of Intent (NOT-AI-02-038) dated July 19, 2002, and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. The BAA indicates "One (1) or two (2)" potential NBL awards, and four (4) to six (6) RBLs in FY '03 and four (4) to six (6) RBLs in Fy'04. See page 5, paragraph 6, of the BAA anticipated funds available.

Question 14 The BAA refers to a cost share of 25% for the awardee (pg 7, para. 2). Does this provision apply to the construction cost of the NBL? The operation of the NBL?

Yes, for construction costs. The details of the separate operations and management contract have not been determined and are not within the scope of this BAA.

Question 15 Should there be escalation of construction costs, justified claims, force majeure, etc., during the construction phase; what is NIAID's commitment to cover these costs that are above the original project estimate?

It is anticipated that the prime contractor will negotiate a construction contract that is legally sound and that limits the liability of the purchaser. Please review the FAR Clauses contained in the solicitation for General Clauses that are required to be in subcontracts issued under the prime. These FAR clauses include provisions for Claims and Acts of God or nature. NIAID will commit to a maximum amount authorized for construction subcontracts. Therefore, a "Guaranteed Maximum Price" may be negotiated between the prime and subcontractors. Changes to the maximum amount authorized for a subcontract must be negotiated in advance. The following clauses will more than likely be included in any resultant contract:

FAR 52.236-1 Performance of Work by the Contractor
FAR 52.236-2 Differing Site Conditions
FAR 52.236-4 Physical Data
FAR 52.236-5 Material and Workmanship
FAR 52.236-7 Permits and Responsibilities
FAR 52.236-8 Other Contracts
FAR 52.236-10 Operation and Storage Areas
FAR 52.236-11 Use and Possession Prior to Completion
FAR 52.236-12 Cleaning Up
FAR 52.236-13 Accident Prevention
FAR 52.236-15 Schedules for Construction Contacts
FAR 52.236-18 Work Oversight in Cost-Reimbursement Construction Contracts
FAR 52.236-21 Specifications and Drawings for Construction
FAR 52.236-27 Site Visit
FAR 52.246-12 Inspection of Construction

Question 16 The BAA states that "The facility must be utilized for biomedical research projects as determined by NIAID program needs" (pg. 7, para. 6). Our Institution has biodefense contracts from several Federal agencies. Can this work or similar work be performed in the NBL? Or only work funded/approved by NIAID? What specific restrictions on the use of the facility are contemplated?

The facility must give priority to Regional Centers of Excellent for Biodefense and Emerging Infectious Diseases (RCEs), followed by other NIAID funded biodefense research, and finally to biodefense work funded by other agencies and entities. See page 5, paragraphs 2 and 3 of the BAA.

Question 17 Will the Federal Government provide liability insurance, indemnification or other relief regarding the operation of an NBL4?

See question #9, above, regarding insurance for the operation of the facility. Indemnification requires a review and approval process specific to individually awarded contracts. After award of an operating contract, as applicable, the review process can be requested, considered and initiated.

Question 18 Intergovernmental Review, page 11, paragraph 2. Can we assume that only the SPOC of the State where the NBL is sited need be advised and not the states "served by" the NBL?

Yes.

Question 19 In the event that the contract is cancelled by the government prior to completion of construction, what provisions will there be for recovery of cost share and site restoration?

Cost recovery in the event of contract termination will occur in accordance with applicable contract termination clauses and the Federal Acquisition Regulation (FAR).

Question 20 Is this now being conducted as a Grant opportunity? I saw on the NIAID Biodefense site that a BAA has been opened. How does that relate to and impact this requirement?

The BAA includes both NBLs and RBLs. We anticipate that the NBLs will be awarded as contracts, and the RBLs as grants. This solicitation package clearly identifies the portions of this package applicable to the submission of a grant application vs. a contract proposal.

Question 21 What is the status of the Architectural programming and design of NIAID laboratories and centers? Is there is a new website? Will additional comment solicitations (such as at Marriott Gaithersburg in August) be occurring.

Our ongoing website is still available but there are no plans for a new website or for additional meetings.

Question 22 Can the grant for the building include costs for outfitting the building with equipment and tables and chairs, etc.

No. See http://grants1.nih.gov/grants/policy/nihgps/part_iii_1.htm and page 5, last paragraph, of the BAA and for more information regarding allowable costs.

Question 23 Could staff who are Army employees, participate as collaborators in our proposal, and if so, are there any limitations?

We are interested in perhaps seeking cooperation and collaboration of Argonne Labs as a co-applicant in our process for bringing either an RBL or NBL to our area. As you know, Argonne Labs is supported by the Department of Defense (thus Federal). Would they be eligible to play a key role (i.e.- as co-applicant) on our applications?

No. Only domestic, non-Federal, non-profit organizations are eligible to apply. See page 7 of the BAA.

Question 24 On page 5 of the RFP for the Regional Biodefense Laboratories Contract states that applicants must be associated with or linked to existing or planned Regional Centers of Excellence and on page 7 it states that the Applicant must be associated with or have planned links to one or more institutions or consortia that are applying for NIAID RCE grant awards. Could you clarify for me if an application for a RCE planning grant, which requires the intent to submit for a full RCE, satisfies the requirement of the RBL application qualifications for a link to a planned RCE?

Yes.

Question 25 What will be the "ownership" arrangement of the NBL facility?

The applicant institution, not the NIH, will be the owner of the building.

Question 26 **Cost Sharing / Matching Funds**

1) If an institution or consortium has an existing facility or one under construction that is an enhanced BSL3, BSL3Ag and /or BSL4, could it be used toward part of the minimal match requirement? As an example, if there was a hypothetical $25 million dollar BSL3+ and BSL4 lab under construction, currently, could that $25 million dollars be considered part of their minimum match requirement?

2) The BAA specifically states that land and off site improvements are not to be counted in cost share. Are there any other stipulations regarding what can or cannot be counted towards the cost share?

3) Can land be part of the match?

4) The insistence on a 25% cash match will be difficult for our group to raise. We would hope that the NIH would lower that number and also would consider contributions in kind such as land cost, space in building that is under construction and incorporation of existing animal space into the NBL to count for this match.

5) Since the matching fund requirement caught us by surprise, and the time to submission is very short, it will not be possible to obtain a secure commitment for funds prior to submission. We believe that the state will provide funding but the legislature does not convene until after the deadline. How do you suggest we handle this? Also, can we borrow the funds?

6) Will the value of existing applicant owed land and buildings, and the cost of recent building renovations, be considered as "funds" for the purpose of meeting the $3/$1 funding match requirement?

7) Can you provide clarification on the matching funds eligibility requirement in the NBL solicitation? Specifically, does the $1 to $3 have to be cash dollars, or can in-kind contributions include the value of assets such as existing facilities, equipment, and directly relevant capital investments to be applied to the project, or other sources of ongoing revenue, waived fees/allowable costs, etc.? Also, how important is the matching requirement with respect to the overall evaluation criteria for award?

Cost sharing/matching fund contributions for the NBL/RBLs must consist of non-Federal funds designated for the project. The source and amount of funds proposed by an applicant to meet a matching requirement must be identified in the application. The applicant will be required to demonstrate that the funds are committed or available prior to the award. Required non-Federal participation may be in the form of allowable costs incurred by the grantee or a contractor under the grant. The only pre-award costs that can be used to satisfy part of the matching requirement are costs incurred before an award for architect's fees and consultant's fees necessary to the planning and design of the project, assuming the project is subsequently approved and funded. Any other pre-award costs, including land and buildings, cannot be counted as matching funds.

Allowable costs (Pre-award):

a. Costs incurred before an award for architect's fees and consultant's fees necessary to the planning and design of the project are allowable if the project is subsequently approved and funded.

Allowable costs (Post-award):

a. Acquisition and installation of fixed equipment.

b. The costs of adapting interior building features to the needs of the grant-supported activity.

c. Architectural and engineering services.
d. Bid advertising.
e. Bid guarantees, performance and payment bonds.
f. Contingency fund.
g. Filing fees for recording the Notice of Federal Interest.
h. Inspection fees.
i. Insurance.
j. Legal fees related to obtaining a legal opinion regarding title to site.
k. Preaward costs: Project management.
l. Relocation expenses.
m. Sidewalks necessary for use of the facility.
n. Site survey and soil investigation.
o. Site clearance (as long as reflected in bid).

Unallowable costs:
a. Bonus payments to contractors, including guaranteed maximum price contracts.
b. Construction of shell space designed for completion at a future date.
c. Consultant fees not related to actual construction.
d. Damage judgment suits.
e. Equipment purchased through a conditional sales contract.
f. Fund-raising expenses.
g. Land acquisition
h. Legal services not related to site acquisition.
i. Movable equipment.
j. Off-site improvements.

See OER, NIH Grants Policy Statement, Part III, Construction Grants (http://grants1.nih.gov/grants/policy/nihgps/part_iii_1.htm) for details.

Question 27 **On-Site/Off-Site** **(Revised Response: 11/25/02)**

1) Can the grant be for 20 years of lease costs instead of building costs?

2) Can the "Building" be virtual, such that animal facilities for the building could be at one institution, and two other institutions could each put in for BSL-3 space to fit each sites needs?

3) Would a university owned and operated facility on land obtained by long term lease (longer than the 20 year life of the facility) from the U.S. Army be eligible for an NBL or would it be non-responsive as it is off-site?

The grant/contract covers construction but not the cost of a lease.

The facility may be built on land that is leased by the applicant institution. Applicants must include an opinion from acceptable title council describing the interest the applicant organization has in the site and the building and certifying that the estate or interest is legal and valid. If there is a lease, the legal opinion must provide evidence of the existence of a lease agreement which covers a time period sufficient for the usage requirement (20 years beyond completion or occupancy of the project) and that a Federal interest in the building will be recorded for the period of the usage requirement.

The facility may be built on property that is owned by the applicant institution but may be situated at a location other than the main campus. However, it is not possible to apply for one award for construction at multiple sites owned by either the same organization or multiple institutions. Each institution would have to apply for a separate award that would define each individual "construction project".

Question 28 Page 33 of the BAA includes a list of forms applicable to both the RBL and the NBL applications. Please confirm the requirement to include the following forms in the NBL contract proposal. We believe that they are duplicates of other NBL required information (e.g. budget information, certifications and assurances, etc.).

- SF424
- SF424C
- SF424D
- Checklist for NIH Research Facility Construction Grant Application
- Personal Data on Principal Investigator
- Disclosure of Lobbying Activities

Please refer to the Revised RFP (11/5/02), page 30. Form SF424 is to be used for the Technical Proposal Cover Sheet. SF 424C is to be used for the Technical Proposal Cost Information. The remaining NBL only forms/attachments are not considered duplicative.

Question 29 Page 68 of the BAA, Statement of Work, does not clearly indicate whether it is appropriate to include a discussion of building design and construction or a discussion of scientific research that will be carried out in the facility. Specifically we question Objectives, Approach, and Methods.

In the revised RFP, this is page 65, paragraph b.(1)a)(1), (2) and (3). This is boilerplate RFP language. You need to refer to the information on pages 22-23 (revised RFP).

Question 30 What is the nature of the funding for the RBL's? Can the funding be used to construct a new Regional Biocontainment Laboratory?

Yes. Refer to page 5, Part A.

Question 31 Page 36 of the Announcement indicates, "The extent of the offerer's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range." However, the NIAID Contract Management Forms and Attachment web site indicates that the SDB plan is required with the final proposal. Please clarify if the SDB Plan is to be submitted with the application.

Page 57 (revised RFP), paragraph 13, addresses SDB Participation Targets. This information must be provided with the original proposal submission in compliance with instructions on page 33, paragraph B.2. The form on the Forms/Attachments website you are referring to is the Small Business Subcontracting Plan. This is a different document that, as stated, is due with final proposal submission. You may refer to page 56, paragraph (11), for an explanation of this document.

Question 32 Are the research and clinical facilities required to be co-located?

Yes.

Question 33 Our NBL design includes a range of BSL-2, 3 and 4 labs, both animal and non-animal. We have questions as to what is the appropriate mix of the lab types, especially in terms of day-to-day vs. emergency operation. How can we get guidance on this issue?

How much and what kinds of animal space is appropriate?

Refer to Table on page 10 of the RFP for the minimums.

Question 34 We have heard that institutions in our region and in nearby regions are planning to apply for RBLs and RCEs. It would strengthen both their applications and ours if we could coordinate the proposed facilities and activities. Will it be possible to receive a list of institutions which submit letters-of-intent for RCEs in time to coordinate arrangements and incorporate them into our application?

By regulation, we are not allowed to divulge the identies of any offerors who submit intents. You can refer to the following weblink for the August 8 meeting participants list: http://www.niaid.nih.gov/dmid/bioterrorism/rblrce.htm

Question 35 The applicable security standards and setbacks required greatly affect both setting and cost issues. What security standards will apply to the NBLs?

All local, state, and federal codes shall apply. It is encouraged that offerors perform a risk assessment and threat analysis to aide in the development of facility security program requirements.

Question 36 Can the same PI head both the RCE and the NBL from a single applicant or region?

One individual can be the PI for both the RCE and the NBL application within the limits of NIH policy. However, the time and effort required to direct either one of these projects will be substantial, so that a person considering doing both needs to be able to devote sufficient time to meet all of their commitments. In addition, the skills, experience, and expertise needed to manage and direct the two projects are somewhat different.

Question 37 Your answer to Question 26, 2nd posting, dated 11/7/02, leads us to ask two questions. 1) Can we assume that state funds applied to date for this incomplete project be used as the cost sharing/matching contribution in an RBL proposal?

No.

Question 38 And, 2) can we compete for a RBL given the status of our project, i.e., design in progress to renovate a new, previously uncommissioned and unoccupied BSL3-Ag facility?

Yes, but only preaward costs that could be used towards cost sharing are the costs incurred for architect's fees and consultant's fees necessary to the planning and design of the project are allowable if the project is subsequently approved and funded. NIH will not reimburse for prior expenses (except as noted above). You may not use existing facilities for matching funds.

Question 39 We are concerned that the design approval process described in the BAA will delay completion in a timely way.

NIH construction grant policy is not subject to change for this initiative. However, we will work with awardees to expedite the required review and approvals as much as possible.

Question 40 We are not clear about what is meant by the "most stringent interpretation of the BMBL." Is it intended that offerors propose BSL3 or BSL3 Ag space?

The BAA includes a requirement for BSL 3 space. The space proposed may include "BSL3-Ag" space as appropriate . In designing and planning facilities, offerors/applicants should do a needs assessment, a risk assessment, and an analysis of the BMBL guidelines, and then present a plan that meets those needs and provides for a safe and secure facility. As stated in the BAA, flexibility or space usage as well as capacity to adapt to likely changes in requirements should be considerations. The BAA presents the minimum requirements; applicants/offerors are free to expand upon those requirements.

Question 41 RFP Number BAA-NIH-NIAID-NCRR-DMID-03-36, Regional Biocontainment Laboratories (RBL) and National Biocontainment Laboratories (NBL), states "a suitable community relations plan and assurance of acceptance of the intended research activities . must be addressed in the

proposal" and "documentation of community acceptance . before award/construction." (page 26, paragraph 7).

Question 42 What are the acceptable means of documenting community acceptance?

It is the offerors responsibility to develop and implement a proactive community relations plan that will demonstrate effective means of acquiring and subsequently maintaining community acceptance of the RBL/NBL project. The offerors proposal shall include documentation about the steps that have been taken as well as evidence of community opinion regarding the proposed siting of the subject RBL/NBL facility.